Remarks

35 U.S.C. §112 Rejection

Claims 61-68 were rejected under the first paragraph of 35 U.S.C. §112 as failing to comply with the written description requirement. In response, Applicant has canceled claims 61-68, thereby obviating this rejection.

35 U.S.C. §102 Rejection based on Epstein

Claims 36-39, 42-47, and 49 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,226,877 to Epstein ("Epstein"). The Examiner states that:

> Epstein discloses a surgical procedure comprising the steps of removing tissue comprised of blood from a first location (col. 6, lines 1-4), separating one or more components from at least a portion of the tissue by centrifugation (col. 7, lines 13-23), and implanting the packed tissue at a second location (col. 10, lines 45-60).

For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by Epstein.

Epstein teaches a method for preparing fibrinogen adhesive in which the process begins with the withdrawal of whole blood from an autologous, or other, or multiple donors in the presence of an anticoagulant, and separation of plasma from the red blood cell fraction (col. 6, lines 1-4). After the plasma is separated from the red blood cells, it is treated directly, at ambient temperature, without prior treatment to remove thrombin, with a physiologically acceptable non-toxic precipitant (col. 6, lines 16-20). The concentrated solution or, in some instance, undiluted precipitant is added to the plasma in an amount effective to precipitate the fibrinogen adhesive composition of the invention (col. 6, lines 37-40). The precipitate containing the fibrinogen adhesive is then recovered, typically by centrifugation (col. 6, lines 54-55). Commercial preparations of thrombin and calcium ion may be added with the fibrinogen adhesive (col. 10, lines 48-50). In a particularly advantageous way to apply the two components of the sealant to the tissue to be cemented, a dual-barreled applicator with one barrel for supply of the fibrinogen adhesive and the other for the thrombin/calcium ion mixture is employed (col. 10, lines 53-57).

In contrast, Applicant discloses a surgical procedure for tissue harvesting in which hard or

soft tissue of the body is removed for possible re-implantation. Removed tissue may be centrifuged if necessary or desired, keeping the components such as bone, cells, and blood and discarding fluid (col. 9, lines 13-26). The surgeon can place other substances into the graft material to be implanted, such as other tissue graft material, collagen, antibiotics, or ceramic hydroxyapatite or tricalcium phosphate to aid in bone ingrowth (col. 9, lines 27-35) Before implantation, harvested tissue fragments may be packed or compressed into a plug of tissue graft material, of a specific shape, with or without blood or fibrin for adhesion (col. 3, line 68 to col. 4, line 3).

Therefore, the invention as claimed differs from Epstein. For example, one embodiment of the present invention involves removal of blood in conjunction with other tissue types. In contrast, Epstein only removes blood. Additionally, Applicant's tissue graft is shaped, while Epstein does not involve any shaping of the adhesive. At best, the adhesive exits the applicator in the form determined by the nozzle. Epstein places the fibrinogen adhesive into a dual-barrel applicator. An outer lever arm of the applicator is pressed and a predefined amount of adhesive is deposited (col. 14, lines 37-43). Conversely, Applicant's harvested tissue fragments may be packed or compressed into a plug of tissue graft material, or a specific shape (col. 3, line 68 to col. 4, line 2). Applicant shapes the harvested tissue prior to implantation, while Epstein forces the adhesive through the applicator and implants the fibrinogen adhesive to the work surface, simultaneously. Epstein uses a dual-barrel applicator to deposit a predefined amount of adhesive to the work area (see reference above). That is, fibrinogen adhesive is discharged and comes in contact with tissue at the same time. In contrast, Applicant packs or compresses tissue fragments into a plug of tissue having a specific shape, then the graft material is inserted at the graft location (col. 4, lines 1-10).

To further highlight these distinctions of the present invention, Applicant has amended independent claim 36 to recite, *inter alia*, that the removed tissue includes blood and other body tissue. Accordingly, Applicant respectfully submits that independent claim 36 is now in condition for allowance. Based at least on their dependency, Applicant submits that claims 37-39, 42-47 and 49 are allowable as well.

35 U.S.C. §102 Rejection based on O'Leary

Claims 36, 38 and 61-65 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,073,373 to O'Leary *et al.* ("O'Leary"). Specifically, the Examiner states that:

> O'Leary discloses a surgical procedure comprising the steps of removing tissue and blood (col. 1, lines 18-24 and col. 2, line 52 to col. 3, line 14) from a first location, separating one or more components from at least a portion of the tissue (col. 2, lines 14-43), packing the tissue and implanting the packed tissue at a second location (col. 4, lines 13-45), and adding a substance to the packed tissue (col. 2, line 44 to col. 3, line 15).

For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by O'Leary.

O'Leary discloses a flowable demineralized bone powder composition for use in surgical bone repair (col. 1, lines 27-29). The bone powder can be obtained from cortical, cancellous and/or corticocancellous allogenic or xenogenic bone tissue. In general, allogenic bone tissue is preferred as the source of the bone powder (col. 2, lines 10-13). The composition may be packaged or put into a container, thereby making the composition ready for immediate application to a bone defect site employing any suitable means, e.g., a syringe, spatula, etc (col. 4, lines 33-37). Alternatively, the bone powder composition can be prepared well in advance and stored under sterile conditions until required for use, e.g., in the barrel of a syringe or other suitable applicator device (col. 4, lines 42-44).

In contrast, Applicant discloses a surgical procedure for tissue harvesting in which hard or soft tissue of the body is removed for possible re-implantation. In one embodiment, the human tissue grafting is performed using the patient's own tissue as donor material. Therefore, the harvested tissue may be implanted in the donor's own body for grafting (col. 3, lines 57-60). Before implantation, harvested tissue fragments may be packed or compressed into a plug of tissue graft material, of a specific shape, with or without blood or fibrin for adhesion. (col. 3, line 68 to col. 4, line 3).

Therefore, there are distinctions between O'Leary and the present invention.. For example, O'Leary, like Epstein, does not teach or suggest the removal of both blood and other body tissue. With O'Leary, only bone tissue is removed from a donor, treated, and then implanted in a different individual. In discussing the background, O'Leary does note that blood

can be combined with bone, but there is nothing to indicate that the blood and bone are removed at the same time, let alone have a component removed prior to implantation. O'Leary uses allogenic or xenogenic bone tissue to make the bone powder composition while Applicant uses autogenous tissue for grafting. Additionally, O'Leary's bone powder composition is shaped as a result of being implanted in a patient while Applicant packs harvested tissue into a desired shape prior to implanting the tissue in the implant area.

To further highlight these distinctions of the present invention, Applicant has amended independent claim 36. Applicant respectfully submits that amended claim 36 is now in condition for allowance. Based at least on its dependency, Applicant also submits that dependant claim 38 is allowable as well.

35 U.S.C. §103 Rejection based on O'Leary in view of Kambin

Claims 39, 40, 49, 51, 53-55, 57-60, 66, 69, 71 and 73-75 were rejected under 35 U.S.C. §103(a) as being unpatentable over O'Leary in view of U.S. Patent No. 4,573,448 to Kambin ("Kambin"). Specifically, the Examiner states that:

> O'Leary disclosed the claimed invention except for the first tubular member used to cut the tissue from the first location. Kambin teaches a bone-cutting instrument that provides a rotatable cutter and suction (col. 3, lines 47-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the bone cutter of Kambin since Kambin's bone cutter is used to remove bone fragments, which can be used in the method of O'Leary to make the desired bone paste.

For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by O'Leary and Kambin, either alone or in combination.

As previously noted, O'Leary discloses a flowable demineralized bone powder composition that used non-autogenous bone. Kambin does nothing to remedy the deficiencies of O'Leary.

Specifically, Kambin discloses a method for decompressing herniated intervertebral discs in the lumbar region of a human patient (col. 1, lines 8-9). First, a needle with a stylet is introduced through the skin and to the intervertebral disc space. The stylet is then removed and replaced with a guidewire. Next, the needle is removed and a trocar is passed over the guidewire

until it reaches the exterior of the annulus. With the trocar in place, the guidewire is removed and a cannula is passed over the trocar. Next, the trocar is withdrawn and a cutting instrument is introduced into the cannula. Finally, the cutting instrument is manually rotated until a window is formed in the annulus. Meanwhile, suction is applied through the cutting instrument to remove disc fragments (col. 4, lines 14-68).

In contrast, Applicant discloses a surgical procedure for tissue harvesting in which hard or soft tissue of the body is removed for possible re-implantation. In one embodiment, the tissue grafting uses the patient's own tissue as donor material. Therefore, the harvested tissue may be implanted in the donor's own body for grafting (col. 3, lines 57-60). Before implantation, harvested tissue fragments may be packed or compressed into a plug of tissue graft material, of a specific shape, with or without blood or fibrin for adhesion (col. 3, line 68 to col. 4, line 3).

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim language. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *see* §MPEP 2143.

First, there is no motivation or suggestion to modify the references. O'Leary's flowable demineralized bone power composition is used for bone repair. The composition is made from pulverized bone, powered bone, or bone powder taken from allogenic or xenogenic bone tissue. O'Leary uses bone to repair bone. Modifying O'Leary with Kambin is an undesirable combination since the tissue that Kambin removes is intervertebral disc tissue. A disc consists of a central part known as the nucleus, and a surrounding part known as the annulus. Neither the nucleus nor the annulus is made of bone tissue. Therefore, using Kambin's disc tissue to make O'Leary's bone power composition would render O'Leary's bone composition unsatisfactory for its intended purpose. The proposed modification of O'Leary changes the principle of operation of the O'Leary reference.

Second, there is no reasonable expectation of success from combining or modifying O'Leary and Kambin. As stated above, O'Leary teaches a bone powder composition while Kambin teaches the removal of intervertebral disc tissue (non-bone tissue). A successful bone powder composition applied to the site of a bone defect, e.g. one resulting from injury, infection, malignancy or development malformation, leads to rapid new bone ingrowth by one or more mechanisms such as osteogenesis, osteoconduction and osteoinduction. A bone powder composition made from disc tissue has no expectation of success.

Finally, even if the references are combined as suggested by the Examiner, the present invention would still not be obtained. For example, Applicant uses autogenous tissue for implantation, while O'Leary uses allograft tissue and Kambin doesn't teach implantation of tissue. O'Leary discloses a flowable demineralized bone powder composition for use in surgical bone repair. The bone powder can be obtained from cortical, cancellous and/or corticocanellous allogenic or xenogenic bone tissue. In general, allogenic bone tissue is preferred as the source of the bone powder. Conversely, Applicant discloses a surgical procedure for tissue harvesting in which hard or soft tissue of the body is removed for possible re-implantation. Thus, unlike O'Leary and Kambin, Applicant re-implants tissue in a patient taken from the patient. O'Leary's composition may be packaged or put into a container, thereby making the composition ready for immediate application to a bone defect site employing any suitable means, e.g., a syringe, spatula, etc. Alternatively, the bone powder composition can be prepared well in advance and stored under sterile conditions. Kambin teaches the removal of an intervertebral disc using a rotating cutting instrument and suction to remove the nucleus and annulus from the patient. In contrast, Applicant removes tissue from a patient and re-implants the harvested tissue back into the patient's own body for grafting.

Furthermore, one embodiment of the present invention uses a flexible drill shaft so that the cutting tip used to remove tissue can be guided into various locations, e.g. to cut around arcs or angles. O'Leary has no disclosure of a cutting tool and Kambin, uses a tube member and is silent as to the ability to flex the shaft. In order to highlight this distinction, claim 40 now recites, *inter alia*, that the elongated member through which force is transmitted to the cutting tool is flexible such that the cutting tool can be guided.

Based on the foregoing, Applicant respectfully submits that claims 39, 40, 49, 53, 60, 69, and 71 are patentably distinct over O'Leary and Kambin. Based on at least their dependency, Applicant submits that dependent claims 51, 54, 55, 57-59, and 73-75 are patentable as well. Alternatively, regarding claim 39 and 49, Applicant submits that these claims are patentably distinct since claims 39 and 49 depend from amended claim 36 (*see above*, §102 Rejection based on O'Leary).

35 U.S.C. §103 Rejection based on O'Leary in view of Bagby

Claim 41 was rejected under 35 U.S.C. §103(a) as being unpatentable over O'Leary in view of U.S. Patent No. 4,936,848 to Bagby ("Bagby"). Specifically, the Examiner states that:

> O'Leary discloses the claimed invention except for the removal of tissue from the second location. Bagby teaches that diseased tissue must be removed before an implant is inserted into the body (col. 4, lines 54-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the step of removing tissue from the second location in order to remove diseased or damaged tissue before the implant was inserted.

For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by O'Leary and Bagby, either alone or in combination. In particular, Bagby does nothing to remedy the deficiencies of O'Leary.

Bagby discloses a spherical vertebral implant for use between opposing vertebrae in a spine to selectively promote arthrodesis or arthoplasty (col. 3, lines 35-39). The present method for selectively promoting arthrodesis or arthroplasty between vertebrae can best be understood from a study of FIGs. 3-7. The operating surgeon must partially or completely remove a ruptured, flattened or degenerated disc located between the centrums of a pair of adjacent vertebrae having opposed facing surfaces (col. 4, lines 51-57).

In contrast, Applicant discloses a surgical procedure for tissue harvesting in which hard or soft tissue of the body is removed for possible re-implantation. In one embodiment, the tissue grafting uses the patient's own tissue as donor material. Therefore, the harvested tissue may be implanted in the donor's own body for grafting (col. 3, lines 57-60). The specification discloses that to implant one or more selected components of the harvested tissue fragments, a cannula can

be inserted through the skin and muscle to the area of the bone where the graft is to be placed. A curette or probe is then inserted through the cannula to clear out the areas where the graft is to be placed (col. 9, lines 51-57).

Applicant respectfully submits that the Examiner has not established a prima facie case of obviousness. First, there is no motivation or suggestion to modify the references. O'Leary's flowable demineralized bone power composition is used for bone repair. The composition is made from pulverized bone, powered bone, or bone powder taken from allogenic or xenogenic bone tissue. O'Leary uses bone to repair bone. Modifying O'Leary with Bagby is an undesirable combination since Bagby removes a ruptured, flattened or degenerated disc. As described above, disc tissue is not bone tissue. Therefore, using Bagby's disc tissue to make O'Leary's bone power composition would render O'Leary's bone composition unsatisfactory for its intended purpose. The proposed modification of O'Leary changes the principle of operation of the O'Leary reference.

Second, there is no reasonable expectation of success from combining or modifying O'Leary and Bagby. As discussed in O'Leary, a successful bone powder composition applied to the site of a bone defect leads to rapid new bone ingrowth by one or more mechanisms such as osteogenesis, osteoconduction and osteoinduction. A bone powder composition made from disc tissue has no expectation of success.

Finally, the claimed invention is not taught or suggested by O'Leary and Bagby. First, O'Leary teaches that bone powder can be obtained from cortical, cancellous and/or corticiocancellous allogenic or xenogenic bone tissue, while Bagby states that an operating surgeon must partially or completely remove a ruptured, flattened or degenerated disc located between the centrums of a pair of adjacent vertebrae. Neither O'Leary nor Bagby discloses the step of moving a surgical instrument through a cannula. Applicant uses a curette or probe inserted through the cannula to clear out the area where the graft is to be placed. Second, Bagby teaches the removal of a ruptured disc, while O'Leary teaches nothing about the removal of tissue. Additionally, neither Bagby nor O'Leary teaches the removal of tissue from a first location and a second location. In contrast, Applicant teaches percutaneous tissue removal from one location, then removing tissue from a second location with a curette or probe so tissue from

the first location may be implanted in the second location.

Based on the foregoing, Applicant respectfully submits that claim 41 is patentable over O'Leary and Bagby.

35 U.S.C. §103 Rejection based on O'Leary in view of Kambin, Muller-Lierheim, and Amrani

Claims 52, 67, 68, 70 and 72 were rejected under 35 U.S.C. §103(a) as being unpatentable over O'Leary in view of Kambin and further in view of U.S. Patent No. 4,828,563 to Muller-Lierheim ("Muller-Lierheim") and U.S. Patent No. 4,210,580 to Amrani ("Amrani"). Specifically, the Examiner states that:

> O'Leary, as modified, discloses the closed invention except for centrifuging the blood or body tissue to separate one or more components from the blood. Muller-Lierheim teaches that growth factors, particularly fibronectin, are added to bone implants to enhance biocompatibility and mechanical strength (col. 1, line 37 to col. 2, line 7). Amrani teaches that fibronectin may be obtained from blood plasma by centrifuging the blood plasma (col. 2, lines 26-30). It would have been obvious to one having ordinary sill in the art at the time the invention was made to provide the method of O'Leary with the additional step of centrifuging blood to obtain fibronectin, an additive to an implant material, to enhance the biocompatibility and strength of the O'Leary implant material.

In response, Applicant respectfully submits that this rejection is in error and should be withdrawn. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *see* MPEP §2143.

Regarding claim 52, Applicant submits that this claim is patentably distinct since claim 52 depends from independent claim 53 (*see above*, §103 Rejection based on O'Leary in view of Kambin).

Regarding claims 67 and 68, Applicant submits that these claims are patentably distinct since claims 67 and 68 depend from independent claim 61 (*see above*, §102 Rejection based on O'Leary).

Regarding claim 70, Applicant submits that this claim is patentably distinct since claim 70 depends from independent claim 69 (*see above*, §103 Rejection based on O'Leary in view of Kambin).

Regarding claim 72, Applicant submits that this claim is patentably distinct since claim 72 depends from independent claim 71 (*see above*, §103 Rejection based on O'Leary in view of Kambin).

35 U.S.C. §103 Rejection based on O'Leary in view of Kambin and Bagby

Claims 56 and 76 were rejected under 35 U.S.C. §103(a) as being unpatentable over O'Leary in view of Kambin and further in view of Bagby. Specifically, the Examiner states that:

> O'Leary, as modified, discloses the claimed invention except for the removal of tissue from the second location. Bagby teaches that diseased tissue must be removed before an implant is inserted into the body (col. 4, lines 54-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary, as modified, with the step of removing tissue from the second location in order to remove diseased or damaged tissue before the implant was inserted.

For the reasons set forth below, Applicant respectfully submits that the rejected claims are not taught or suggested by O'Leary, Kambin, and Bagby, either alone or in any combination. In particular, the disclosures of each of these references have been previously discussed and Applicant respectfully submits that the Examiner has not established a prima facia case of obviousness.

First, there is no motivation or suggestion to modify the references. O'Leary's flowable demineralized bone power composition is used for bone repair. The composition is made from pulverized bone, powered bone, or bone powder taken from allogenic or xenogenic bone tissue. O'Leary uses bone to repair bone. Modifying O'Leary with Kambin and Bagby is an undesirable combination since Kambin and Bagby remove an intervertebral disc. As described above, disc tissue is not bone tissue. Therefore, using Kambin's or Bagby's disc tissue to make O'Leary's bone power composition would render O'Leary's bone composition unsatisfactory for its intended purpose. The proposed modification of O'Leary changes the principle of operation of the O'Leary reference.

Second, there is no reasonable expectation of success from combining or modifying O'Leary with Kambin and Bagby. As discussed in O'Leary, a successful bone powder composition applied to the site of a bone defect leads to rapid new bone ingrowth by one or more mechanisms such as osteogenesis, osteoconduction and osteoinduction. A bone powder

composition made from disc tissue has no expectation of success.

Finally, the invention recited in claims 56 and 76 is not taught or suggested by O'Leary, Kambin, and Bagby. First, none of the cited references teaches a first tubular member at a first location and a second tubular member at a second location. Instead, O'Leary teaches that the bone powder composition can be stored in the barrel of a syringe or other suitable applicator device. Kambin teaches that a cannula is held firmly against the annulus and a cutting instrument is introduced. Bagby does not teach the use of a tubular member. Conversely, Applicant discloses a flexible inner cutting shaft having a suction passage for harvested tissue fragments to travel (col. 6, lines 4-29), as well as a cannula inserted through the skin to the implant area (col. 9, lines 51-57). Second, O'Leary, Kambin, and Bagby do not teach the step of moving a surgical instrument through the second tubular member. Since none the references teach a second tubular member, there is no disclosure of a surgical instrument in a second tubular member. In contrast, Applicant discloses a cannula which is inserted through the skin to the area where the graft is to be placed. A curette or probe is inserted through the cannula to clear out the area where the graft is to be placed. Third, none of the cited references discloses the step of removing tissue from a second location with a surgical instrument. O'Leary doesn't teach the removal of tissue from the body, while Kambin and Bagby both disclose the removal of tissue from just one location. In contrast, as stated above, Applicant removes tissue from a first location using a tissue removal apparatus and removes tissue from a second location using a curette or probe inserted through a cannula.

In light of the foregoing, Applicant respectfully submits that claims 56 and 76 are patentable of O'Leary in view of Kambin and Bagby.

If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *see* MPEP §2143. Therefore, regarding claim 76, Applicant submits that this claim is patentably distinct since claim 76 depends from independent claim 69 (*see above*, §103 Rejection based on O'Leary in view of Kambin).

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

Conclusion

In light of the foregoing, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due with this submission. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-014-8).

Respectfully submitted,

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